



**SOURCE:**

[https://www.phmpt.org/wp-content/uploads/2022/04/reissue\\_5.3.6-postmarketing-experience.pdf](https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf)

**Pfizer's Conclusion:**

In this SOC, as with a number of other medical conditions, the conclusion of Pfizer was, "This cumulative review does not raise new safety issues. Surveillance will continue." Additionally, they state:

Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, noninterventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals.

The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June 2021)

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This SOC shows a relatively large number of events. **This one syndrome made up 1% of the entire post-marketing patients reporting adverse events.** The rate of facial weakness/paralysis clearly attracted enough attention so that, in spite of Pfizer's usual denial of significance, they identified studies that would produce a larger data set. However, since finalizing the 5.3.6 report in February 2021, **there has been no further summary data released for outside review.** Furthermore, a search on <https://clinicaltrials.gov/> for the cited studies (C4591011 and C4591012) yielded no studies found (accessed February 23, 2023).



Another observation by the Post-Marketing Team involved Pfizer's decision to remove this facial paralysis syndrome from the Neurologic SOC and report it separately, which **dilutes the larger issue of neurologic events after vaccination.**

Additionally, it is surprising that Pfizer used limited search criteria for this SOC. Usual medical as well as lay terminology would call this condition Bell's palsy. However, the available search terms nowhere indicate a search under this diagnosis. Similarly, a closely related condition, Ramsay Hunt syndrome, was not searched. **The failure to use all common terms may have resulted in the adverse events being understated.**

**Post-Marketing Team's CONCLUSION**  
**RECALL this unsafe "vaccine."**

